

DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2012-0081]

Qualification of Drivers; Application for Exemption; Implantable Cardioverter Defibrillator

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA has received applications from three individuals with implantable cardioverter defibrillators (ICDs) for an exemption from the cardiovascular disease standard in the Federal Motor Carrier Safety Regulations (FMCSRs). The Agency's current advisory criteria for the applicable FMCSR recommends that CMV drivers with ICDs should not be qualified due to the likelihood of causing a loss of ability to operate a commercial motor vehicle (CMV) safely. If granted, an exemption would allow these individuals with ICDs to operate a CMV in interstate commerce.

DATES: Comments must be received on or before [Insert date 30 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA-2012-0081 using any of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the on-line instructions for submitting comments.
- Mail: Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, S.E., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

1

- Hand Delivery: West Building Ground Floor, Room W12-140, 1200 New Jersey
 Avenue, S.E., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through
 Friday, except Federal Holidays.
- Fax: 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to http://www.regulations.gov, including any personal information provided. Please see the Privacy Act heading below for further information.

<u>Docket</u>: For access to the docket to read background documents or comments, go to http://www.regulations.gov at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, S.E., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgment page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the <u>Federal Register</u> on January 17, 2008 (73 FR 3316).

FOR FURTHER INFORMATION CONTACT: Charles Horan, Director, Office of Carrier, Driver, and Vehicle Safety Standards (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue, S.E., Room W64-(306), Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

FMCSA has the authority to grant exemptions from the FMCSRs; pursuant to 49 U.S.C. 31315 and 31136(e) as amended by Section 4007 of the Transportation Equity Act for the 21st Century (TEA- 21) [Pub. L. 105-178, June 9, 1998, 112 Stat. 107, 401]. On August 20, 2004, FMCSA published a final rule implementing the changes made by section 4007 (69 FR 51589). The current regulations require FMCSA to publish a notice of each exemption request in the Federal Register. The Agency must provide the public with an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request (49 CFR 381.315(a)).

The Agency reviews the safety analyses and the public comments and determines whether granting the exemption would likely achieve a level of safety equivalent to or greater than the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the Federal Register (49 CFR 381.315(b)). If the Agency denies the request, it must state the reason for doing so. If the Agency decision is to grant the exemption, the notice must specify the person or class of persons receiving the exemption and the regulatory provision or provisions from which an exemption is granted. The notice must also

specify the effective period of the exemption (up to 2 years) and explain the terms and conditions of the exemption. If granted, the exemption may be renewed (49 CFR 381.315(c) and 381.300(b)).

The three individuals included in this notice have each requested an exemption from the provisions of 49 CFR 391.41(b)(4), which applies to drivers who operate CMVs in interstate commerce, as defined in 49 CFR 390.5. Section 391.41(b)(4) states that:

"...a person is physically qualified to drive a commercial motor vehicle if that person has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (temporary loss of consciousness due to a sudden decline in blood flow to the brain), dyspnea (shortness of breath), collapse, or congestive cardiac failure."

The FMCSA provides medical advisory criteria as recommendations for use by medical examiners in determining whether drivers with certain medical conditions, procedures, and/or treatments should be certified to operate CMVs in interstate commerce in accordance with the various physical qualification standards in 49 CFR part 391, subpart E. The advisory criteria are currently set out as part of the medical examination report published with 49 CFR 391.43. The advisory criteria for section 391.41(b)(4) provide that:

The term "has no current clinical diagnosis of" is specifically designed to encompass: "a clinical diagnosis of" (1) a current cardiovascular condition, or (2) a cardiovascular condition which has not fully stabilized regardless of the time limit. The term "known to be accompanied by" is designed to include a clinical diagnosis of a cardiovascular disease (1) which is accompanied by symptoms of syncope, dyspnea, collapse or congestive cardiac failure; and/or (2) which is likely to cause syncope, dyspnea, collapse, or congestive cardiac failure. It is the intent of the FMCSRs to render unqualified, a driver who has a current cardiovascular disease which is accompanied by and/or likely to cause symptoms of syncope, dyspnea, collapse, or congestive cardiac failure. However, the

subjective decision of whether the nature and severity of an individual's condition will likely cause symptoms of cardiovascular insufficiency is on an individual basis and qualification rests with the medical examiner and the motor carrier.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted may place the driver at risk for syncope (a transient loss of consciousness) or other gradual or sudden incapacitation that may result in loss of ability to safely control a CMV. When an ICD deploys, the driver experiences a loss of ability to safely control a CMV. See the conference report on Cardiovascular Advisory Panel Guidelines for Medical Examination of Commercial Motor vehicle Drivers at 94-95 (2002)¹.

Individual Applications for Exemption - Qualifications

James Dean

Mr. Dean is a 53 year old CMV driver who holds a class A and a class D commercial driver's license (CDL) from the State of Wisconsin. He has driven a CMV for over 29 years. Mr. Dean had an ICD placed due to ventricular tachycardia and a low ejection fraction which improved. The device deployed in 2011. Mr. Dean would like to continue to drive a truck in interstate commerce.

Mark Steiner

Mr. Steiner is a 64 year old CMV driver who holds a class A CDL from the state of Ohio. He has driven a CMV for 38 years. Mr. Steiner had angioplasty and stent placement after he had a heart attack while driving (first cardiac event in his life) in January 2012. The ICD was placed preventively in November 2012 after he completed cardiac rehabilitation. The device has not deployed. Mr. Steiner would like to continue to drive a truck in interstate commerce.

5

¹ Now available at http://www.fmcsa.dot.gov/documents/cardio.pdf (retrieved July 22, 2013

Craig Bohms

Mr. Bohms is a 57 year old owner operator of a CMV who holds a class A commercial driver's license (CDL) from the State of Illinois. According to Mr. Bohms, following a heart attack in April 2013 he was implanted with an ICD. In an August 2013 letter that was submitted by Mr. Bohms electrophysiologist (EP) physician, he stated "Mr. Bohms was implanted with an ICD as a preventative measure to protect him from possible ventricular tachycardia... from an EP standpoint, Mr. Bohms is able to drive and return to work without restrictions". Mr. Bohms would like to continue to drive a truck in interstate commerce.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption if it makes a finding that the exemption "would likely achieve a level of safety that is equivalent to or greater than that would be achieved absent such an exemption." FMCSA requests public comment from all interested persons on the exemption application described in this notice. In accordance with 49 U.S.C. 31315(b)(4), and 49 CFR 381.315(b) and (d), the safety analysis or assessment, and other supporting information is available for examination and review. The Agency will consider all comments received before the close of business [Insert date 30 days after date of publication in the FEDERAL REGISTER]. Comments will be available for examination in the docket at the location listed under the ADDRESSES

section of this notice. The Agency will file comments received after the comment closing date in

the public docket, and will consider them to the extent practicable. In addition to late comments,

FMCSA will also continue to file, in the public docket, relevant information that becomes

available after the comment closing date. Interested persons should monitor the public docket for

new material.

Issued on: January 10, 2014.

Larry W. Minor,

Associate Administrator for Policy.

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7